DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 9, 2015

Halyard Health (formerly known as Kimberly-Clark Health Care)
Thomas Kozma, Ph.D.
Director of Regulatory Affairs
5450 Windward Parkway
Alpharetta, GA 30004

Re: K142782
Trade/Device Name: KIMGUARD* ONE-STEP® Sterilization Wrap
(Models KC100, KC200, KC300, KC400, KC500, and KC600)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: February 12, 2015
Received: February 13, 2015

Dear Dr. Kozma,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Post market Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*

K142782

Device Name

KIMGUARD* ONE-STEP® Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600)

Indications for Use *(Describe)*

KIMGUARD ONE-STEP® Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using:

- V-PRO® 60 Low Temperature Sterilization System that include:
  - Lumen Cycle
  - Non Lumen Cycle
  - Flexible Cycle

KIMGUARD ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.

Test results validated that KIMGUARD ONE-STEP® Sterilization Wraps (KC100, KC200, KC300, KC400, KC500, and KC600) allowed sterilization of the enclosed devices by the V-PRO® 60 Low Temperature Sterilization System (i.e., Lumen, Non Lumen, and Flexible Cycles). Additionally, the KIMGUARD ONE-STEP® Sterilization Wrap was validated to allow effective aeration under the pre-programmed sterilization cycles.

All models of the KIMGUARD ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, and KC600) have been validated for use with the V-PRO® 60 Low Temperature Sterilization System cycles in Table 1.

KIMGUARD ONE-STEP® Sterilization Wraps (KC100, KC200, KC300, KC400, KC500, and KC600) Recommendations for Use with the V-PRO® 60 Low Temperature Sterilization System are provided in Table 2.

***TABLE 1: Validated* V-PRO® 60 Low Temperature Sterilizer System Cycles**

V-PRO® 60 Low Temperature Sterilizer Cycles	Intended Load

Lumen Cycle	Reusable metal and non-metal medical devices including instruments with diffusion-restricted spaces (such as the hinged portion of forceps or scissors) and single, dual or triple channeled rigid/semi-rigid endoscopes, with the following configurations:
	• Single or dual channeled devices with stainless steel lumens with
	  ○ An inside diameter of 0.77 mm or larger and a length of 410 mm or shorter
	• Triple channeled devices with stainless steel lumens with
	  ○ An inside diameter of 1.2 mm or larger and a length of 257 mm or shorter.
	  ○ An inside diameter of 1.8 mm or larger and a length of 310 mm or shorter or
	  ○ An inside diameter of 2.8 mm or larger and a length of 317 mm or shorter

Non Lumen Cycle	Reusable metal and non-metal non-lumened medical devices including non-lumened rigid, semi-rigid and flexible endoscopes and medical devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps or scissors.
Flexible Cycle	Single or dual channeled Flexible Surgical Endoscopes or Bronchoscopes with lumens that have: • An inside diameter of 1 mm or larger and a length of 990 mm or shorter.

***TABLE 2: Recommended Loads for KIMGUARD ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, & KC600) for use with* V-PRO® 60 Low Temperature Sterilizer System**

KIMGUARD® ONE-STEP® Sterilization Wrap Models	Intended Loads[1]	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]	Description of Loads Used in Sterility Maintenance Validation Study[2]
KC100	Very Light Weight Package (for example batteries)	3 lbs.	3 lb of metal mass 6 surgical forceps 1 self-contained biological indicator (SCBI) (no tray was included)
KC200	Light Weight Package (for example telescope with light cord)	6.5 lbs.	• 2.5 lbs metal mass • 6 surgical forceps • 1 SCBI • V-PRO tray (17" x 10" x 3½") at 4 lbs
KC300	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs.	• 5 lbs metal mass • 6 surgical forceps • 1 SCBI • V-PRO tray (17" x 10" x 3½") at 4 lbs
KC400	Moderate to Heavy Weight Package (for example: general use medical instruments)	12 lbs.	• 8 lbs metal mass • 6 surgical forceps • 1 SCBI • V-PRO tray (17" x 10" x 3½") at 4 lbs
KC500	Heavyweight Package (for example: general use medical instruments)	12 lbs.	• 8 lbs metal mass • 6 surgical forceps • 1 SCBI • V-PRO tray (17" x 10" x 3½") at 4 lbs
KC600	Very Heavy Weight Package (for example: general use medical instruments)	12 lbs.	• 8 lbs metal mass • 6 surgical forceps • 1 SCBI • V-PRO tray (17" x 10" x 3½") at 4 lbs

[1] Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for KIMGUARD ONE-STEP® Sterilization Wraps.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant's Name, Address, Telephone, FAX, Contact Person:

Halyard Health (formerly known as Kimberly-Clark Health Care)
5450 Windward Parkway, Alpharetta, GA 30004, USA

Establishment Registration Number: 1033422

Contact Name: Thomas Kozma, Director of Regulatory Affairs
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DATE PREPARED:	March 6, 2015
TRADE NAME:	KIMGUARD* ONE-STEP® Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600)
CLASSIFICATION NAME:	Sterilization Wrap
COMMON/USUAL NAME:	Sterilization Wrap
PRODUCT CODE:	FRG
DEVICE CLASSIFICATION:	Class II per 21 CFR §880.6850
PREDICATE DEVICES:	K092167 and K112805 - KIMGUARD* ONE-STEP® Sterilization Wrap (Models KC100, KC200, KC300, KC400, KC500, and KC600).

INDICATIONS FOR USE

KIMGUARD ONE-STEP® Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using:

- V-PRO® 60 Low Temperature Sterilization System that include:
  - Lumen Cycle
  - Non Lumen Cycle
  - Flexible Cycle

KIMGUARD* ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.

Test results validated that KIMGUARD ONE-STEP® Sterilization Wraps (KC100, KC200, KC300, KC400, KC500, and KC600) allowed sterilization of the enclosed devices by the V-PRO® 60 Low Temperature Sterilization System (i.e., Lumen, Non Lumen, and Flexible Cycles). Additionally, the KIMGUARD ONE-STEP® Sterilization Wrap was validated to allow effective aeration under the pre-programmed sterilization cycles. All models of the KIMGUARD ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, and KC600) have been validated for use with the V-PRO® 60 Low Temperature Sterilization System cycles in TABLE 1.

TABLE 1: Validated *V-PRO® 60 Low Temperature Sterilizer System Cycles*	
Cycles	**Intended Load**
Lumen Cycle[1]	Reusable metal and non-metal medical devices including instruments with diffusion-restricted spaces (such as the hinged portion of forceps or scissors) and single, dual or triple channeled rigid/semi-rigid endoscopes, with the following configurations: • Single or dual channeled devices with stainless steel lumens with o An inside diameter of 0.77 mm or larger and a length of 410 mm or shorter • Triple channeled devices with stainless steel lumens with o An inside diameter of 1.2 mm or larger and a length of 257 mm or shorter. o An inside diameter of 1.8 mm or larger and a length of 310 mm or shorter or o An inside diameter of 2.8 mm or larger and a length of 317 mm or shorter
Flexible Cycle[1]	Single or dual channeled Flexible Surgical Endoscopes or Bronchoscopes with lumens that have: • An inside diameter of 1 mm or larger and a length of 990 mm or shorter.
Non-Lumen Cycle[1]	Reusable metal and non-metal non-lumened medical devices including non-lumened rigid, semi-rigid and flexible endoscopes and medical devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps or scissors.

KIMGUARD ONE-STEP® Sterilization Wraps (KC100, KC200, KC300, KC400, KC500, and KC600) Recommendations for Use with the V-PRO® 60 Low Temperature Sterilization System are provided in TABLE 2.

TABLE 2: Recommended Loads for KIMGUARD ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, & KC600) for use with ***V-PRO® 60 Low Temperature Sterilizer System***

Wrap Models	Intended Loads[1]	Maximum Wrapped Package Content Weights MPI Study[2]	Description of Loads Used in Sterility Maintenance Validation Study[2]
KC100	Very Light Weight Package (for example batteries)	3 lbs.	3 lb of metal mass 6 surgical forceps 1 self-contained biological indicator (SCBI) (no tray was included)
KC200	Light Weight Package (for example telescope with light cord)	6.5 lbs.	• 2.5 lbs metal mass • 6 surgical forceps • 1 SCBI • V-PRO® tray (17" x 10" x 3½") at 4 lbs
KC300	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs.	• 5 lbs metal mass • 6 surgical forceps • 1 SCBI • V-PRO® tray (17" x 10" x 3½") at 4 lbs
KC400	Moderate to Heavy Weight Package (for example: general use medical instruments)	12 lbs.	• 8 lbs metal mass • 6 surgical forceps • 1 SCBI • V-PRO® tray (17" x 10" x 3½") at 4 lbs
KC500	Heavyweight Package (for example: general use medical instruments)	12 lbs.	• 8 lbs metal mass • 6 surgical forceps • 1 SCBI • V-PRO® tray (17" x 10" x 3½") at 4 lbs
KC600	Very Heavy Weight Package (for example: general use medical instruments)	12 lbs.	• 8 lbs metal mass • 6 surgical forceps • 1 SCBI • V-PRO® tray (17" x 10" x 3½") at 4 lbs

[1] Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for KIMGUARD ONE-STEP® Sterilization Wraps.

DESCRIPTION OF DEVICE

KIMGUARD* ONE-STEP® Sterilization Wrap is comprised of two sheets of KIMGUARD* Sterilization Wrap that is ultrasonically seamed on two edges. This seamed configuration allows for convenient wrapping of an article using two sheets simultaneously.

The blue or white sheets of sterilization wrap are square or rectangular fabric produced using a three-layer SMS (spunbound-meltblown-spunbound) process. The blue wrap fabric is composed of polypropylene with the addition of less than 2% by weight of phthalocyanine blue pigment, less than 1% by weight titanium dioxide pigment, and less than 0.008% by weight of anti-static treatment. The white sheet has the same material composition but contains no blue pigment. The wrap allows a sterilized package to be opened aseptically.

SUBSTANTIAL EQUIVALENCE TO PREDICATE DEVICE

KIMGUARD ONE-STEP® Sterilization Wrap (i.e., subject of this Premarket Notification) is substantially equivalent to the predicate Kimberly-Clark KIMGUARD* ONE-STEP® Sterilization Wraps (K092167 & K112805) in technology, design, and materials.

The following table compares the subject KIMGUARD* ONE-STEP® Sterilization Wrap to the predicate KIMGUARD* ONE-STEP® Sterilization Wrap.

DEVICE COMPARISON TABLE (TECHNOLOGICAL, DESIGN, & MATERIALS)

Characteristics	Predicate Devices: KIMGUARD* ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, & KC600) (K092167 & 112805)	Proposed Device: KIMGUARD* ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, & KC600)
Manufacturer	Kimberly-Clark Corporation	Kimberly Clark Corporation
Regulation/Product Code	Sterilization Wrap: 880.6850 / FRG	Sterilization Wrap: 880.6850 / FRG
Indications for Use	The device is intended to be used to enclose another medical device that is to be sterilized by a healthcare provider by the Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System's Lumen (identical to the V-PRO™ 1 Cycle) and Non-Lumen Cycles, and the V-PRO™ Low Temperature Sterilization System's Flexible Cycle. The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until opened within the period of time for which performance data demonstrating maintenance of sterility has been provided. The KIMIGUARD ONE-STEP* Sterilization Wrap was validated to be effectively aerated during the pre-programmed V-PRO™, V-PRO™ 1 Plus, and V-PRO™ Flexible Cycles.	KIMGUARD ONE-STEP® Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using: • V-PRO® 60 Low Temperature Sterilization System that include: ○ Lumen Cycle ○ Non Lumen Cycle ○ Flexible Cycle KIMGUARD* ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500 and KC600) are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.
Sterilization Cycles	Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System's Lumen (identical to the V-PRO™ 1 Cycle) and Non-Lumen Cycles, and the V-PRO maX Low Temperature Sterilization System's Flexible Cycle	V-PRO® 60 Low Temperature Sterilization System: ○ Lumen Cycle ○ Non Lumen Cycle ○ Flexible Cycle
Maintenance of Package Sterility	For models KC100, KC200, KC300, K400, KC500, and KC600 for at least 30 days.	Real-time testing following sterilization using the V-PRO® 60 Low Temperature Sterilization System supports maintenance of package sterility for 180 days for all models of KIMGUARD* ONE-STEP® Sterilization Wrap.
Technology	Tortuous sheet material used to enclose medical devices that are to be sterilized by a healthcare provider to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.	Tortuous sheet material used to enclose medical devices that are to be sterilized by a healthcare provider to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.
Device Design	Two sheets of nonwoven polypropylene fabric. Each sheet is composed of three thermally- bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbound polypropylene layers (SMS)	Two sheets of nonwoven polypropylene fabric. Each sheet is composed of three thermally- bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbound polypropylene layers (SMS)
Method for bonding SMS layers	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)
Materials	Polypropylene with blue and white pigments	Polypropylene with blue and white pigments
Distribution	Non-Sterile and Over-the-Counter	Non-Sterile and Over-the-Counter
Single Use Device	Yes	Yes

SUMMARY OF NONCLINICAL TESTS

Performance of KIMGUARD* ONE-STEP® Sterilization Wrap (KC100, KC200, KC300, KC400, KC500, KC600) has been tested in accordance with the applicable requirements. All results of testing met acceptance criteria demonstrating that the KIMGUARD* ONE-STEP® Sterilization Wrap allows sterilization of contents by the V-PRO® 60 Low Temperature Sterilization System (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) and maintains sterility of contents until used.

Summary of Testing Performed	Results
V-PRO® 60 Low Temperature Sterilization System Sterilant Penetration	Passed
Post V-PRO® 60 Low Temperature Sterilization System Sterilization - Maintenance of Package Integrity (30 Days)	Passed
Post V-PRO® 60 Low Temperature Sterilization System Sterilization - Performance Testing	Passed
Post V-PRO® 60 Low Temperature Sterilization System Sterilization - Material Biocompatibility	Passed

OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the KIMGUARD* ONE-STEP® Sterilization Wrap performs as intended as a sterilization packaging system of medical devices when terminally sterilized in the V-PRO® 60 Low Temperature Sterilization System (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle). These studies demonstrate that the KIMGUARD* ONE-STEP® Sterilization Wrap met the same criteria as the predicate devices and are substantially equivalent.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

Based on the intended use, technological characteristics, performance data and nonclinical tests performed, the subject KIMGUARD* ONE-STEP® Sterilization Wrap is substantially equivalent and is as safe and as effective as the legally marketed predicate devices, K092167 and K112805.